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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-11-0073; NOP-11-14]

National Organic Program: Notice of Final Guidance on Certification Requirements for Handling Unpackaged Organic Products

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of availability of final guidance.

SUMMARY: The National Organic Program (NOP) is announcing the availability of a final guidance document intended for use by accredited certifying agents, certified operations and non-certified handlers of certified organic products. The guidance document is entitled: Certification Requirements for Handling Unpackaged Organic Products (NOP 5031). This guidance document is intended to inform the public of NOP's current thinking on this topic.

DATES: The final guidance document announced by this notice is effective on [INSERT DATE 1 DAY AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Melissa Bailey, Ph.D., Director, Standards Division, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave., SW., Room 2646-So., Ag Stop 0268, Washington, DC 20250, Email: Melissa.bailey@ams.usda.gov; Telephone: (202) 720-3252; Fax: (202) 205-7808.

SUPPLEMENTARY INFORMATION:

I. Background

On February 3, 2012, the National Organic Program (NOP) published in the Federal Register a notice of availability with request for public comment on a draft guidance document addressing the certification requirements for handlers of unpackaged products (76 FR 5415).

The NOP selected the topic for the draft guidance in response to a recommendation issued by the National Organic Standards Board (NOSB) in October 2010. On October 28, 2010, the NOSB finalized a recommendation requesting that the NOP clarify the requirements and limitations of 7 CFR section 205.101(b) of the USDA organic regulations.¹ This section of the regulations addresses the conditions that a handling operation must meet in order to be excluded from the organic certification requirements of 7 CFR Part 205. The NOSB recommended that the NOP issue guidance to clarify how these conditions apply to handlers of bulk, unpackaged organic products. The draft guidance can be viewed on the NOP website at <http://www.ams.usda.gov/NopDraftGuidance>. The 60-day comment period closed on April 3, 2012.

NOP received approximately 25 individual comments on the draft guidance document. Based upon the comments received, the NOP revised and is publishing a final guidance document on Certification Requirements for Handling Unpackaged Organic Products (NOP 5031). The guidance document includes an appendix (NOP 5031-1) where the NOP provides a complete discussion of the comments received and the rationale behind any changes made to the guidance documents.

In addition to responding to the NOSB's October 2010 recommendation, this final guidance addresses a finding from a February 2012 Office of Inspector General (OIG) audit and a July 2013 OIG audit on organic milk.² The OIG audits stated that the NOP needs to ensure that organic milk is not coming into contact with prohibited substances while being transported. In

¹ NOSB Recommendation: Clarifying Limitations of § 205.101(b). Issued on October 28, 2010. Available on the NOP website at: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5087789&acct=nosb>

² February 2012 OIG Audit on National Organic Program: Organic Milk. Available on the NOP website at: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5100590>. July 2013 OIG Audit on National Organic Program: Organic Milk. Available from OIG at: <http://www.usda.gov/oig/webdocs/01601-0002-32.pdf>

OIG's recommendations, it stated that the NOP should ensure that transporters are either certified or included in the responsible parties' Organic System Plan (OSP).

In response to the OIG, this final guidance clarifies that transporters of unpackaged bulk products such as organic milk are not considered handlers under the USDA organic regulations and, therefore, do not need to obtain certification. The guidance states that it is the certified organic operation responsible for the organic products that are transported who must prevent commingling and contamination of the organic products during transportation, fully describe the transportation practices in their organic system plan, maintain sufficient records for the auditing and traceability of transported organic products, and ensure that the transportation records for organic products are available for inspection. This approach ensures that certifying agents have oversight regarding the transport of unpackaged organic products through their certified operations and can ensure that prohibited substances have not come into contact with these products through a complete, verifiable audit trail.

The final guidance is available from the NOP through "The Program Handbook: Guidance and Instructions for Accredited Certifying Agents (ACAs) and Certified Operations". This Handbook provides those who own, manage, or certify organic operations with guidance and instructions that can assist them in complying with the USDA organic regulations. The current edition of the Program Handbook is available online at <http://www.ams.usda.gov/nop>.

II. Significance of Guidance

This final guidance document is being issued in accordance with the Office of Management and Budget (OMB) Bulletin on Agency Good Guidance Practices (GGPs) (January 25, 2007, 72 FR 3432-3440). The purpose of GGPs is to ensure that program guidance documents are developed with adequate public participation, are readily available to the public, and are not applied as binding requirements. This guidance represents the NOP's current

thinking on the topic. It does not create or confer any rights for, or on, any person and does not operate to bind the NOP or the public. Guidance documents are intended to provide a uniform method for operations to comply with the Organic Foods Production Act (OFPA) and the USDA organic regulations that can reduce the burden of developing their own methods and simplify audits and inspections. Alternative approaches that can demonstrate compliance with the OFPA, as amended (7 U.S.C. 6501-6522), and its implementing regulations are also acceptable. As with any alternative compliance approach, the NOP strongly encourages industry to discuss alternative approaches with the NOP before implementing them to avoid unnecessary or wasteful expenditures of resources, and to ensure the proposed alternative approach complies with the OFPA and its implementing regulations.

Electronic Access

Persons with access to Internet may obtain the final guidance at the NOP's website at <http://www.ams.usda.gov/nop>. Request for hard copies of the final guidance document can be obtained by submitting a written request to the person listed in the FOR FURTHER INFORMATION CONTACT section of this Notice.

Authority: 7 U.S.C. 6501-6522.

Dated: January 15, 2014

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